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EXAMINER	
CHEN, CATHERYNE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,043	TAN ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,25 and 37-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,25 and 37-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on Dec. 28, 2007 has been received and entered. Claims 1, 25 and 37-56 are pending. Claims 1, 25 and 37-56 will be examined on the merits. Claims 2-24, 26-36 are canceled.

Election/Restrictions

Based on the response to the restriction requirement filed July 21, 2005, without traverse, Applicant elected Group I and the species that was elected was palm extract.

Response to Arguments

Specification

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant contends that there is no new matter because they are incorporated by reference. Applicant has many references and nowhere is the disclosure of a 350-450D molecular fraction cited. Applicant is only entitled to the molecular weight of the different forms of tocopherol, not the range of molecular weights, which can encompass chemicals other than tocopherols. As to Applicant argument that inherent functions may be later added, it is noted in 2163.07(a) that "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949,

1950-51 (Fed. Cir. 1999) (citations omitted). Applicant failed to point out that the molecular weight range is essential in the original specification. Furthermore, in Applicant's argument regarding incorporation by reference, it is noted in 2163.07(b) that "Replacing the identified material incorporated by reference with the actual text is not new matter." Applicant failed to specifically identify the material that is encompassed by the molecular range. Thus, the molecular weight mentioned in Table 1 is not new matter, but the claimed ranges are considered new matter. Applicant is required to cancel the new matter in the reply to this Office Action, unless Applicant can cite where this molecular range was specified and claimed by the Applicant.

Claim Rejections - 35 USC § 112

Claims 39, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is over the recitation "a 350-450 Dalton MW fraction of". There is no support in the originally filed instant specification or originally filed claims for "a 350-450 Dalton MW fraction of". Applicant alleges that the support is from a new Table that they want to insert in the specification, the Declaration by Dr. Tan file June 4, 2007, alleges that they teach different molecular weights of tocopherols and tocotrienols. This does not provide support for the claimed range. Thus, "a 350-450 Dalton MW fraction of" finds no support from the instant specification. Thus, an attempt to limit molecular weights of tocotrienols and tocopherols adds new

matter. Applicant contends that there is no new matter because they are incorporated by reference. Applicant has many references and nowhere is the disclosure of a 350-450D molecular fraction sighted. Applicant is only entitled to the molecular weight of the different forms of tocopherol, not the range of molecular weights, which can encompass chemicals other than tocopherols. Applicant is required to cancel the new matter in the reply to this Office Action, unless Applicant can sight where this molecular range was specified and claimed by the Applicant.

Claims 39, 47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions ofExparte Steigewald, 131 USPQ 74 (Bd. App. 1961); Exparte Hall, 83 USPQ 38 (Bd. App. 1948); and Exparte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claim 25 recites the broad recitation "fibers," and the claim also recites

"(insoluble and soluble types, including beta-glucans)" which is the narrower statement of the range/limitation. Also, claim 25 recites the broad recitation "omega-3 s," and the claim also recites "(DHAs and EPAs, alpha linoleic acid)" which is the narrower statement of the range/limitation. Also, claim 25 recites the broad recitation "banaba extract," and the claim also recites "(including corosolic acid)" which is the narrower statement of the range/limitation. Also, claim 25 recites the broad recitation "lipoic acid," and the claim also recites "(all isomeric forms)" which is the narrower statement of the range/limitation. In claim 39, it is not clear if the oily byproduct extract of Bixa orellana seed has tocopherol levels of 50% or if the natural extract has tocopherol levels of 50%. Clarification is needed. Applicant's amendment of adding "vegetable" before "natural extract" did not clarify the claim language.

Claim 39 recites the limitation "the level of tocopherol" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

In claims 39-41, the claims are unclear due to the comparative basis of the term "the level." What is this being compared to? Clarification is needed.

In claim 47, it is not clear if the oily byproduct extract of Bixa orellana seed where the delta-tocotrienol and gamma-tocotrienol comprise > 50% of the tocotrienols in the composition or if the natural extract does. Clarification is needed. Applicant's amendment of adding "vegetable" before "natural extract" did not clarify the claim language.

Claim 47 recites the limitation "the tocotrienols" in line 3. There is insufficient antecedent basis for this limitation in the claim.

In claim 49, it is not clear if the oily byproduct extract of Bixa orellana seed has C5 unsubstituted tocotrienols of >60% and tocopherols of <15%. Clarification is needed.

In claim 50, it is not clear if the oily byproduct extract of Bixa orellana seed has C5 unsubstituted tocotrienols of >80% and tocopherols of <5% or if the natural extract does. Clarification is needed. Applicant's amendment of adding "vegetable" before "natural extract" did not clarify the claim language.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 25, 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453) in view of Meijer et al. (US 6,787,151) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that amendments overcome the rejection.

Tan (US 6,350,453) discloses that byproduct of Bixa orellana seed contains tocotrienols including delta- and gamma- tocotrienols (col. 3, lines 31-33). Tan also disclose that tocotrienols have beneficial effects as antioxidants and possess hypocholesterolemic effects (col. 1, lines 12- 17). However, Tan does not disclose the ratio between delta-tocotrienol and gamma-tocotrienols or oryzanois, policosanols, pentathine, red yeast rice (Monascus), oat bran, garlic, gugul lipids, oligo-peptides, CoQ 10, carnitine, magnesium, calcium, D-tyroxine, fibers (insoluble and soluble types,

including beta-glucans), omega-3s (DHAs and EPAs, alpha linoleic acid), banaba extract (including corosolic acid), lipoic acids (all isomeric forms), Vitamin B 1 (Thiamine), Vitamin B2 (Riboflavin), Vitamin B5 (Pantothenic acid), Vitamin B6 (Pyridoxine and Pyridoxamine), Vitamin B7 (Biotin), Vitamin B9 (Folic acid) or Vitamin B 12 (Cyanocobalamin).

Meijer et al. (US 6,787,151) disclose ingestable materials such as tocotrienols, pantethine, calcium, magnesium, L-carnitine, fibers, oryzanol and vitamins B6 and B 12 as improvements in cholesterol status or potential cholesterol improvements (col. 2, lines 43-48; col. 4, line 3; col. 9, lines 25-26 and 61-66).

It would have been obvious to one of ordinary skill in the art at the time of invention was made to use the oily by-product of Bixa orellana, which contains both delta- and gamma- tocotrienols, as taught by Tan and combine the delta- and gamma-tocotrienol extract with pantethine, calcium, magnesium, L-carnitine, fibers, oryzanol and vitamins B6 and B 12 as taught by Meijer to form a composition to treat cholesterol. One would have been motivated to use the oily byproduct of Bixa orellana that contains delta- and gamma-tocotrienol, with any one of the ingredients that Meijer discloses because the Bixa orellana seed extracts, tocotrienols, and pantethine, calcium, magnesium, L-carnitine, fibers, oryzanol or vitamins B6 and B 12 are all known to treat cholesterol. Akhough none of the references disclose specifically the ratios between delta-tocotrienols and gamma-tocotrienols, the instantly claimed ratio range encompasses a ratio of 1:1 which would be an obvious ratio for one of ordinary skill in the art to employ based upon the beneficial teachings provided by the cited reference

with respect to each of these ingredients having bioactivity, thus incorporating equal amounts thereof so as to provide such bioactivity would have been obvious to the skilled artisan having the references before him/her as a guide. Therefore, one of ordinary skill in the art would have a reasonable amount of success to use the oily byproduct of Bixa orellana that contains delta- and gamma-tocotrienol, with any one of the ingredients that Meijer discloses because the Bixa orellana seed extracts, tocotrienols, and pantethine, calcium, magnesium, L-carnitine, fibers, oryzanol or vitamins B6 and B12 are known to treat cholesterol.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that treat cholesterol. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423,426 (1971); In re Crockett, 47 CCPA 1018,' 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that each of these substances are used in compositions to treat cholesterol, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat cholesterol. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable

invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; • In re Crockett 126 USPQ 186. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited references.

Claims 39-46, 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453) in view of Frega et al. ("Identification and Estimation of Tocotrienols in the Annatto Lipid Fraction by Gas Chromatography-Mass Spectrometry," JAOCS; Vol. 75; No. 12; pages 1723-1727; (1998)), Kamat et al. ("Tocotrienols from Palm oil as effective inhibitors of protein oxidation and lipid peroxidation in rat liver microsomes," Molecular and Cellular Biochemistry: 170: pages 131-138; 1997) and Waggle et al. (US 6,669,952) in light of Internet website "R&D Chemicals "Genistin" for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the amendment overcome the rejection.

Tan (US 6,350,453) discloses that there is essentially no alpha-tocopherol present in the oily byproduct of Bixa orellana (col. 2, lines 45-47). Tan discloses that byproduct of Bixa orellana seed components is byproduct oil (col. 50-60; col. 6, lines 1-2, 23). However, Tan does not disclose where the level of tocopherol is specifically

50% or 20% or 1% or where the tocopherol is alpha-tocopherol or where the level of alpha-tocopherol is 50% or 20% or 1% or having a molecular weight of 350-450 of a natural extract.

Frega et al. teach that lipid fraction extracted from annatto seeds (Bixa orellana) completely lacks in tocopherols (page 1725, col. 1, 2nd paragragh).

Kamat et al. teach tocotrienol-rich fraction of palm oil (i.e. natural extract) is considered more effective as a natural antioxidant than alpha-tocopherol (see abstract).

Waggle et al. (US 6,669,952) teach that plant sterols, soy protein and isoflavones are known to reduce total cholesterol and LDL-cholesterol in the blood of animals (col. 1, lines 12- 15, 41-42). Obtained from soybeans, isoflavones and their naturally occurring glycosides and glycosides conjugates including genistin (i.e. natural extracts) are used in composition for lowering blood cholesterol (col. 6, lines 6-10).

It would have been obvious to one of ordinary skill in the art at the time of invention was made to use the oily byproduct of Bixa orellana, which contains essentially no alpha-tocopherol present in the byproduct, as taught by Tan and Frega and to add a natural extract such as palm oil to the oily byproduct. As taught by Kamat, palm oil is a rich source of vitamin E, containing both tocotrienols and tocopherols. However, Kamat teaches that tocotrienols are considered a more effective natural antioxidant than that of alpha-tocopherol. One would have been motivated to use the essentially alpha-tocopherol-free oily byproduct of Bixa orellana with palm oil because the protective ability (i.e. antioxidant) of tocotrienol-rich fraction was significantly higher than that of alpha-tocopherol. Kamat teaches that the tocotrienol-rich fraction is considered an

effective natural antioxidant supplement capable of protecting cellular membranes against oxidative damage (i.e. having antioxidant properties). One of ordinary skill in the art would be motivated to use very low amounts of alpha-tocopherol in a composition because as disclosed by Kamat, the tocotrienol rich palm oil has been tried as a more economical and efficient substitute for alpha-tocopherol. Additionally, genistin, as taught by Waggle, is used in compositions to lower cholesterol. Therefore, one would have been motivated to use the oily by-product of Bixa orellana with palm oil and genistin (a natural extract) for a composition to lower cholesterol. Antioxidants are known in the art to lower cholesterol as evidenced by Jackson (US 6,040,333)(col. 3, lines 13-14). Although none of the reference disclose specifically the levels oftocopherol and alpha- tocopherol as being 50% or 20% or 1%, as Tan and Frega disclose essentially no alpha- tocopherol is present. Thus, they would meet the limitations of the levels of alpha-tocopherol as "essentially no" would be considered 1%. Therefore, one of ordinary skill in the art would have a reasonable amount of success in using the essentially alpha-tocopherol-free oily byproduct ofBixa orellana with palm oil because alpha-tocopherol does not have the significant antioxidant activity as tocotrienols and would more economical and efficient substitute for alpha- tocopherol. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited references.

Claims 47-48, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tan (US 6,350,453) in view of Frega et al. ("Identification and Estimation of Tocotrienols in the Annatto Lipid Fraction by Gas Chromatography-Mass Spectrometry," JAOCS; Vol. 75; No. 12; pages 1723-1727; (1998)) and Waggle et al. (US 6,669,952) in light of Internet website "R&D Chemicals "Genistin".

Tan (US 6,350,4530) teaches that byproduct extract of Bixa orellana seed components contain tocotrienols including delta- and gamma-tocotrienols (col. 3, lines 31-33). The tocotrienol composition is distilled to increase the concentration of tocotrienol in a range between about 20 weight percent to about 90 weight percent (col. 5, lines 40-42). Additionally, Tan discloses that tocotrienols act as antioxidants and have cholesterol lowering properties (col. 1, lines 12-18). However, Tan does not teach specifically the delta-tocotrienol being > 50% or having a molecular weight of 350-450 of a natural extract.

Frega et al. teach that Bixa orellana seed contains an oily byproduct (i.e. lipid) extract and that the fatty-soluble antioxidant fraction contained only tocotrienols mainly delta-tocotrienols (see abstract and page 1723, col. 2, 3rd paragraph).

Waggle et al. (US 6,669,952) teach that plant sterols, soy protein and isoflavones are known to reduce total cholesterol and LDL-cholesterol in the blood of animals (col. 1, lines 12-15, 41-42). Obtained from soybeans, isoflavones and their naturally occurring glycosides and glycosides conjugates including genistin (i.e. natural extracts) are used in composition for lowering blood cholesterol (col. 6, lines 6-10). It would have been

obvious to one of ordinary skill in the art at the time of invention was made to combine the oily by-product of Bixa orellana, which contains both delta-tocotrienol and gamma-tocotrienol, and has cholesterol lowering properties, to be combined with genistin (a natural extract). Genistin, as taught by Waggle, is used in compositionsto lower cholesterol. Therefore, one would have been motivated to use the oily by-product of Bexar orellana with genistin (a natural extract) for a composition to lower cholesterol. One would have been motivated to use a large amount oftocotrienols in the composition because of the beneficial properties that tocotrienols are known to have, such as lowering cholesterol lowering effects. Although Tan does not specifically disclose that the level of delta- tocotrienol is greater than 50%, Frega discloses that Bixa orellana contains large quantities of mainly delta-tocotrienols. Furthermore, since tocotrienols are used in compositions for lowering cholesterol, the source of the higher amount of tocotrienol would be from the oily byproduct of Bixa orellana. Furthermore, as disclosed in Waggle, soybean isoflavones, such as genistin, have cholesterol lowering properties. Regarding the molecular weight of a natural extract in claim 47, as evidenced by "R&D Chemicals," 'genistin' has a molecular weight of 432 (see page 2 of reference provided). Therefore, one of ordinary skill in the art would have a reasonable amount of success in combining the oily byproduct of Bixa orellana, that contains both deka-tocotrienol and gamma- tocotrienol, with genistin because Bixa orellana and genistin have cholesterol lowering properties which are known to have beneficial effects.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that lower cholesterol. It is well known that

it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to lower cholesterol, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to lower cholesterol. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was primafacie obvious to one of Ordinary skill in the art at the time the invention was made, as evidenced by the cited references.

Claims 49-50 are rejected under 35 U.S.C.. 103(a) as being unpatentable over Tan (US 6,350,453) in view of Waggle et al. (US 6,669,952)in light of Internet website "R&D Chemicals "Genistin".

Tan (US 6,350,453) teaches that byproduct extract ofBixa orellana seed components contain tocotrienols and essentially has no tocopherol present in the byproduct solution of Bixa orellana (col. 2, lines 40-45). Tan discloses that rice bran oil is mixed with the tocotrienol composition to increase the tocotrienol amount from about 30% to about 45% by weight (col. 4, lines 33-46). The tocotrienol composition is further distilled to increase the concentration of tocotrienol in a range between about 20 weight percent to about 90 weight percent (col. 5, lines 40-42). However, Tan does not teach that the tocopherol levels are 15% or the tocotrienols are C5 unsubstituted tocotrienols or a molecular weight of 350-450 fraction of a natural extract.

Waggle et al. (US 6,669,952) teaches that plant sterols, soy protein and isoflavones are known to reduce total cholesterol and LDL-cholesterol in the blood of animals (col. 1, lines 12- 15, 41-42). Obtained from soybeans, isoflavones and their naturally occurring glycosides and glycosides conjugates including genistin (i.e. natural extracts) are used in composition for lowering blood cholesterol (col. 6, lines 6-10).
It would have been obvious to one of ordinary skill in the art at the time of invention was made to combine the oily by-product of Bixa orellana, which contains tocotrienol and essentially no tocopherol, with a natural extract, such as genistin, because of the cholesterol lowering properties of both Bixa orellana and genistin. Genistin, as taught by Waggle, is used-in compositions to lower cholesterol and are by products of soybean

isoflavones. One would have been motivated to use the oily byproduct ofBixa orellana because Bixa contains tocotrienols, which are known to lower cholesterol, and essentially contain no tocopherols. Although, none of the references disclose C5 unsubstituted tocotrienol, the disclosure states that "it is known that the structural isomeric form oftocols (either tocopherols or tocotrienols) that confers the greatest potency has no substitution in the carbon-5 (C5) position" (page 15, [0019]. Although Tan does not specifically disclose that tocopherols are 15%, Tan does disclose that the tocopherols are essentially non-existent in the oily by-product of Bixa orellana so therefore, the tocopherol would be 15%. Furthermore, genistin, as taught by Waggle, is used in compositions to lower cholesterol. Regarding the molecular weight of a natural extract in claim 47, as evidenced by "R&D Chemicals," 'genistin' has a molecular weight of 432 (see page 2 of reference provided). One would have been motivated to use the oily by-product of Bexar orellana with genistin (a natural extract) for a composition to lower cholesterol. These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that lower cholesterol. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423,426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188. (1960). Based on the disclosure by these references

that these substances are used in compositions to lower cholesterol, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to lower cholesterol. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect 0fthe ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

Thus, one of ordinary skill in the art would have a reasonable amount of success in combining the oily byproduct of Bixa orellana with genistin, a natural extract, because both Bixa orellana and genistin have cholesterol lowering properties which is known in the art. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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